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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/746,311	12/21/2000	Nicole Suciu-Foca	58332-B/JPW/AJM/DRM	9607

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EXAMINER

BELYAVSKYI, MICHAEL A

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 03/11/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/746,311

Applicant(s)

SUCIU-FOCA ET AL.

Examiner

Michail A Belyavskyi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 27-42 and 66-69 is/are pending in the application.
- 4a) Of the above claim(s) 27-37, 41 and 66-69 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 38-40 and 42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 December 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 13.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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## DETAILED ACTION

*Claims 27-42 and 66-69 are pending.*

1. Applicant's election with traverse of Group V claims 38-40 and 42 and ILT4 as species of monocytes inhibitory receptor in Paper No. 16 is acknowledged. The traversal is on the grounds that the inventions must be both independent and distinct and an undue search burden on the examiner. However, MPEP 803 states that the Inventions be either independent or distinct and a burden on the Examiner if restriction is required.

Regarding applicant's comments about undue burden, the MPEP 803 (August 2001) states that "For purposes of the initial requirement, a serious burden on the examiner may be prima facie shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search". The Restriction Requirement enunciated in the previous Office Action meets this criterion and therefore establishes that serious burden is placed on the examiner by the examination Groups. The Inventions are distinct for reasons elaborated in paragraphs 3-6 of the previous Office Action

The requirement is still deemed proper and is therefore made FINAL.

Upon further consideration the prior art search has been extended to include all species of monocytes inhibitory receptor recited in claim 39.

2. Claims 27-37, 41 and 66-69 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions.

*Claims 38-40 and 42 are under consideration in the instant application.*

3. The specification is objected to under 37 CFR 1.821(d) for failing to disclose SEQ ID NO for the amino acid sequence disclosed on page 112, line 21.

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4. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention *to which the claims are directed*.

5. Formal drawings have been submitted which fail to comply with 37 CFR 1.84:  
Please see the enclosed form PTO-948.

#### INFORMATION ON HOW TO EFFECT DRAWING CHANGES

##### **A. Correction of Informalities -- 37 CFR 1.85**

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the "Notice of Allowability."

Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

##### **B. Corrections other than Informalities Noted by Draftsperson on form PTO-948.**

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

#### **Timing of Corrections**

*Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.185(a). Failure to take corrective action within the set (or extended) period will result in ABANDONMENT of the application.*

Applicant is reminded that changes in the Brief Description of the Drawings will be required in accordance with these changes.

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6. Applicant's IDS, filed 8/13/02 (Paper No. 13), is acknowledged. Applicant asserts that copies of cited publications 3,4,6,8,9,11,18,19 and 25 were attaches as Exhibits 1-9. However, it is noted that there was no such attachment in Paper NO:13, and said citations have been crossed out. Applicant is invited to resubmit such references to complete the instant file. The examiner apologizes for any inconvenience to applicant for having to resubmit such documents.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112.

*The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.*

8. Claims 38-40 and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claim 38 is indefinite and ambiguous in the recitation of " a)contacting the APC with Ts and b) overexpressing mRNA in the APC". It is unclear if mRNA will be expressed in the same APC that were contacting with Ts or if it would be a different APC?

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

*The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.*

Claims 38-40 and 42 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of generating a tolerogenic antigen presenting cell which comprises : a) contacting the APC with Ts, wherein Tc are CD8+Cd28- T cells and b) overexpressing mRNA which encodes an MIR in the said APC, wherein MIR is selected from the group recited in claim 39 does not reasonably provide enablement for a method of generating a tolerogenic antigen presenting cell which comprises : a) contacting the APC with any Ts, and b) overexpressing mRNA which encodes any MIR in the said APC. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with this claim.

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The specification disclosure does not enable one skilled in the art to practice the invention without an undue amount of experimentation.

Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, the limited working examples, the unpredictability in the art and the amount of experimentation required to enable one of skill in the art to practice the claimed invention.

The specification only discloses that contacting the APC with Ts, wherein Tc are CD8+Cd28- T cells and b) overexpressing mRNA which encodes an MIR in the said APC, wherein MIR is selected from the group recited in claim 39 will result in generating a tolerogenic APC ( see fifth series of experiments in particular).

The specification does not adequately teach how to effectively generate a tolerogenic APC using the method comprising contacting the APC with *any* Ts, and b) overexpressing mRNA which encodes *any* MIR in the said APC. The specification does not teach how to extrapolate data obtained from *in vitro* studies , using CD8+Cd28- T cells and mRNA which encodes an MIR recited in claim 39 commensurate in scope with the claimed invention. Therefore, it is not clear that the skilled artisan could predict the efficacy of generating a tolerogenic APC using the method comprising contacting the APC with *any* Ts, and b) overexpressing mRNA which encodes *any* MIR in the said APC exemplified in the specification. Moreover, Applicant acknowledge that: (i) there are still controversy concerning the phenotypic characteristic of T cells and that this controversy leads to the speculation that no distinctive Ts lineage actually exists (page 2 line 25-27 in particular); (ii) generation and characterization of different Ts cell lines have met with limited success ( page 3, line 25-27)(iii ) different Ts cell lines induced early change in the target APC by unknown mechanism (page 69, line 10 in particular) . Moreover, Applicants own data indicated that while transcription of wide array of genes was suppressed in APC in response to CD8+Cd28- T cells stimulation , only a *specific* MIR, such as one recited in claim 39 but not *any* MIR were unregulated in said APC ( see page 146, line 10-20 in particular). Applicant stressed that it is essential for the invention that this upregulated MIR will transmits negative inhibitory signal that is crucial for generating a tolerogenic APC as claimed (see page 146, lines 22-30 in particular)

The specification does not provide sufficient teaching as to how it can be assessed that generating a tolerogenic APC was achieved using the method comprising contacting the APC with *any* Ts, and b) overexpressing mRNA which encodes *any* MIR in the said APC.

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Thus, Applicant has not provided sufficient guidance to enable one skill in the art to use claimed method of generating a tolerogenic antigen presenting cell which comprises : a) contacting the APC with *any* Ts, and b) overexpressing mRNA which encodes *any* MIR in the said APC in manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement. *In re Fisher*, 166 USPQ 18(CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute.

In view of the quantity of experimentation necessary, the unpredictability of the art, the lack of sufficient guidance in the specification, the limited working examples, and the limited amount of direction provided given the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

11. No claim is allowed.

12. The prior art does not teach or suggest the claimed invention recited in claims 38-40 and 42.

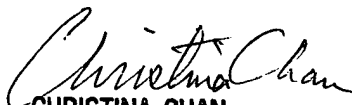
13. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. For example, on page 5, line 25 and on page 131, line 2 the word 'Ts' is misspelled. Applicant's cooperation is requested in correcting any errors of which Applicant may become aware in the specification.

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14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is (703) 308-4232. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Michail Belyavskyi, Ph.D.  
Patent Examiner  
Technology Center 1600  
March 10, 2003

  
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